REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Status of Claims

Claims 48-61 are pending in the application. Claims 48-61 have been rejected. Claims 48, 50-53, 55, and 57-60 have been amended.

Claims 54 and 61 have been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicants reserve all rights in these claims to file divisional and/or continuation patent applications.

CLAIM REJECTIONS

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

In the Office Action, the Examiner rejected claims 48-61 under 35 U.S.C. § 112, first paragraph, for allegedly containing new matter, specifically the limitations "a plurality of *Neisseria* immunotypes," "three or more *Neisseria* immunotypes," "four or more *Neisseria* immunotypes," and "five or more *Neisseria* immunotypes." The Examiner alleged that the term "*Neisseria*" represents the whole genus and encompasses several pathogenic and non-pathogenic species other than *N. meningitidis*, and that the description in Table 2 and page 31, lines 17-18 of the subject specification does not support the "lower and limitless upper range of the new limitations." The Examiner admitted, however, that the cited passages support reactivity of Mab B5 with immunotypes L1, L3, and L7-12 of *N. meningitidis*.

Applicants agree with Examiner's admission that the cited passages support reactivity of Mab B5 with immunotypes L1, L3, and L7-12 of *N. meningitidis*, and respectfully disagree with the rejection.

The Examiner has alleged that the limitation "a plurality of *Neisseria* immunotypes," as recited in claims 48 and 55, is a new limitation whose lower and limitless upper ranges are unsupported in the subject specification.

Applicants respectfully disagree. The first definition of "plurality" in the Merriam-Webster Dictionary is "the state of being plural." Thus, the meaning of the limitation "a plurality of *Neisseria* immunotypes" is "more than one *Neisseria* immunotype." Any number equaling 2 or greater satisfies this limitation. Accordingly, the upper range of *Neisseria* immunotypes recognized is not being addressed by, and thus is not relevant to, this limitation. The lower range of "plurality," the quantity 2, is well defined.

Moreover, in order to expedite prosecution, amended claims 48 and 55 recite "a method for eliciting in a host an antibody that recognizes a plurality of *Neisseria meningitidis* immunotypes (claim 48) or immunizing a host against each of a plurality of *Neisseria meningitidis* immunotypes (claim 55), said *Neisseria meningitidis* immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11, and L12, comprising administering to said host an immunogenic composition, said immunogenic composition comprising an inner core of a *Neisseria* lipopolysaccharide (LPS), wherein a phosphoethanolamine moiety is linked to position 3 of a HepII moiety of said inner core of a *Neisseria* LPS." Support for the amendments is found in the subject specification, *inter alia* in the following passage, which shows that antibodies elicited by the claimed immunogenic composition recognized five *Neisseria meningitidis* immunotypes:

> "Of the 12 immunotypes, MAb B5 recognized the LPS of strains in which the inner core oligosaccharide has a PEtN linked to the 3-position of HepII (Table 2 and Fig. 1). Thus, immunotypes L2, L4, and L6 did not react with MAb B5, whereas ***immunotypes L1, L3, and L7 to L12 were recognized by MAb B5.*** This confirmed that the presence of PEtN in the 3-position of the HepII is necessary to confer MAb B5 reactivity (Fig. 3)" (page 31, second full paragraph; emphasis added).

Thus, 8 *Neisseria* immunotypes were recognized by an antibody of the present invention. Eight is a plurality, as it equals 2 or greater, as described above. Accordingly, the amended claims are clearly directed to an invention that is described and enabled in the subject specification. Applicants therefore respectfully request that the rejection be withdrawn.

The Examiner further alleged that the limitations "three or more *Neisseria* immunotypes," "four or more *Neisseria* immunotypes," and "five or more *Neisseria* immunotypes" as recited in claims 50 and 57; 51 and 58; and 52 and 59, respectively, are new limitations whose lower and limitless upper ranges are unsupported in the subject specification.

In response, in order to expedite prosecution, amended claims 50 and 57; 51 and 58; and 52 and 59 recite the limitations "three or more of said *Neisseria meningitidis* immunotypes," "four or more of said *Neisseria meningitidis* immunotypes," and "five or more of said *Neisseria meningitidis* immunotypes," respectively. Amended claims 53 and 60 recite: "wherein said plurality of *Neisseria* immunotypes comprises all of said *Neisseria meningitidis* immunotypes." Support for the amendments is found in the subject specification, *inter alia* on page 31, second full paragraph, as described hereinabove.

Accordingly, the amended claims are clearly directed to an invention that is described and enabled in the subject specification. Applicants therefore respectfully request that the rejection be withdrawn.

The Examiner further alleged that the subject specification does not provide an enabling disclosure for elicitation of *Neisseria* species other than *N. meningitides*.

In response, in order to expedite prosecution, the amended claims recite that the elicited antibodies recognize *Neisseria meningitidis* immunotypes. Support for the amendments is found in the subject specification, *inter alia* on page 31, second full paragraph, as described hereinabove.

Accordingly, the amended claims are clearly directed to an invention that is described and enabled in the subject specification. Applicants therefore respectfully request that the rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner further rejected claims 50-53 and 60 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Examiner alleged that the limitation "five or more *Neisseria* immunotypes" in claim 53 lacks proper antecedence, and that claims 50-53 and 60 mistakenly recite "whereby" instead of "wherein."

In response, claims 50-53 and 60 have been amended to correct the grammatical errors. Applicants therefore respectfully request that the rejections be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102

The Examiner further rejected claims 48-61 under 35 U.S.C. § 102(b), as being anticipated by Arumugham (EP 0941738), as evidenced by Plested (J Immunol Methods 2000 Apr 3;237(1-2): 73-84, 2000), alleging that Arumugham disclosed a method of immunizing mice with an immunogenic conjugate composition comprising a conserved inner core portion of a meningococcal gonococcal LPS comprising a PEtN group linked to position 3 of HepII of the inner core of the LPS; that the LPS present in the vaccine contains only the conserved core of the LPS structure of the *N. meningitidis* having a structure identified by GlcNAcHep$_2$phosphoethanolamine-KDO$_2$ and is from a galE mutant of *N. meningitidis* wherein no galactose is added to the core portion; and that the prior art method elicted antibodies that recognized or were reactive with a majority of *N. meningitidis* strains. The Examiner further alleged that Plested showed that it was well known in the art the LPS from the prior art galE mutant lacks outer core.

Applicants respectfully disagree. The Examiner alleges that the LPS utilized by Arumugham has a structure identified by GlcNAcHep$_2$phosphoethanolamine-KDO$_2$ (paragraph 46 of Arumugham). Of note, the ***position*** of the PEtN on Hep$_2$ is not specified, either in this section or in the remainder of the document. While the Examiner has alleged that Figures 2 and 3 disclose that the LPS inner core utilized in Arumugham has a PEtN group linked to position 3 of HepII, the specification of Arumugham does not describe these structures as representing the LPS utilized in the experiments conducted therein. Rather, the structures are described as exemplary *Haemophilus* and *Neisseria* structures:

> "***Examples*** of core structures from ***Haemophilus*** and ***Neisseria*** are shown in FIG. 2... Typical examples of completed LOS structures of ***Haemophilus influenzae*** strain 2019...and ***Neisseria gonorrhoeae*** strain 1291...are shown in FIG. 3" (page 2, lines 37-43; emphasis added).

In addition, none of these structures is identified as a structure of a *N. meningitidis* LPS, which was utilized by Arumugham in the experiments described therein (page 8, line 20). By contrast, the structures depicted in Figures 2 and 3 are described as *Neisseria* (no specified species), *N. gonorrhoeae,* or *Haemophilus* LPS structures, as quoted above. Thus, Arumugham makes no representation that the structures disclosed in Figures 2 and 3 represent the LPS utilized therein.

In addition, for 3 of the 4 structures depicted in Figures 2 and 3, the position of the PEtN moiety on HepII is not depicted. Rather, the line connecting PEtN to HepII is drawn to the center of the HepII structure, indicating that the position of HepII is ***unknown***. The only exception is Figure 3B, in which the position of PEtN is indicated; however, this is a structure of an *N. gonorrhoeae* strain (page 4, line 1), and thus is clearly ***not*** the LPS utilized in the experiments described therein, which is a *N. meningitidis* LPS (page 8, line 20).

Thus, Arumugham provides no evidence whatsoever that the immunogenic composition utilized in the methods disclosed therein has a PEtN group linked to position 3 of HepII. By contrast, the subject claims are directed to a method for eliciting in a host an antibody that recognizes a plurality of *Neisseria meningitidis* immunotypes (claim 48) or immunizing a host against each of a plurality of *Neisseria meningitidis* immunotypes (claim 55), said *Neisseria meningitidis* immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11, and L12, comprising administering to said host an immunogenic composition, said immunogenic composition comprising an inner core of a *Neisseria* lipopolysaccharide (LPS), ***wherein a phosphoethanolamine moiety is linked to position 3 of a HepII moiety*** of said inner core of a *Neisseria* LPS." Accordingly, the immunogenic composition utilized by Arumugham lacks a critical element of the immunogenic composition utilized in methods recited in the subject claims. Moreover, Arumugham does not in any way disclose or suggest that the position of the PEtN moiety on HepII is critical to the elicitation of cross-reactive antibodies.

Accordingly, Arumugham does not disclose or suggest the methods recited in the claims of the subject application. Applicants therefore respectfully request that the rejection be withdrawn.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,

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